FDA's Proposed Strategy to Regulate Reprocessing and Reuse of Devices Labeled for Single Use

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Basis of FDA's authority

- Federal Food, Drug, and Cosmetic Act
- 21 Code of Federal Regulations (CFR)
  Parts 800 to 1299

How FDA Classifies Medical Devices

- Class I, Class I exempt
- Class II, Class II exempt
- Class III

Class I

- “General controls” requirements are sufficient to provide reasonable assurance of the safety and effectiveness of the device

General Controls requirements:

- Registration and Listing
- Medical Device Reporting
- Labeling
- Corrections and Removals
- Premarket Notification

Class II

- General controls requirements alone are insufficient to provide reasonable assurance of their safety and effectiveness

- “Special controls”requirements:
  - Promulgation of Performance Standards
  - Postmarket Surveillance
  - Patient Registries
  - Specific Guidelines

Class III

- Requires premarket approval in accordance with section 515 of the FD& C Act

- General and Special Controls requirements are insufficient to provide reasonable assurance of the device’s safety and effectiveness

Types of Premarket Submission

- 510(k) = Substantial Equivalence (SE) to a marketed device
- PMA = a new device not previously marketed or an existing device seeking a new intended use
- Pre-amendment Devices = devices already marketed before 1976

FDA's Current Regulatory Requirements for Third Party Reprocessors of Single-Use Devices (SUDs)

General Controls requirements:

- Registration and Listing
- Medical Device Reporting
- Manufacturing requirements under Quality Systems Regulation
- Labeling Requirements

FDA's Current Requirements for Hospitals Reprocessors of SUDs

- Compliance Policy Guide (CPG) 300.500 (issued 11-11-77)
- Hospitals:
  - Assume full liability and responsibility for their reprocessing actions;
  - Should ensure that the devices are adequately cleaned and sterilized; and
  - Should ensure that devices safety, effectiveness and quality are maintained.

May 5 - 6, 1999

FDA and AAMI (Association for the Advancement of Medical Instrumentation) co-sponsored conference on Reuse of SUDs

FDA's Proposed Strategy

- Nov. 3, 1999 - FDA published "FDA's Proposed Strategy on Single-Use Devices"
  - (www.fda.gov\cdrh\reuse)
- FDA proposes to regulate OEMs, third-party and hospital reprocessors equally

FDA's Proposed Strategy con't.

December 18, 1999

- FDA's Open Public Meeting

FDA's Proposed Strategy con't.

- Feb. 8, 2000: FDA issued 2 draft guidances:
  - "Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme"
  - "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals"

RPS and Enforcement Guidances

- DOES NOT APPLY TO:
  - Permanently implantable pacemakers (CPG 7124.12 issued on Oct. 1, 1980 and revised Mar. 1995)
  - “Opened-but-unused” SUDs
  - Health care facilities that are not hospitals

Risk Prioritization Scheme Guidance

- Assigns an overall risk to SUDs known to be reprocessed by addressing:

1. the risk of infection (flow chart 1) and

2. the risk of inadequate performance after undergoing reprocessing (flow chart 2)

Flow Chart 1: Infection Risk

- 1. Is the SUD a non-critical device?
- 2. Any data to suggest the reprocessed SUD poses an increase risk of infection vs. new SUD?
- 3. Any features to impede thorough cleaning, disinfection and/or sterilization?
- 4. Is there a reusable device of equivalent design and intended use?
- 5. Are there any recognized consensus performance standards, CDRH guidance, etc., to determine if SUD adequately cleaned, disinfected/sterilized?
- 6. Is this a semi-critical device?

Flow Chart 2 - Inadequate Performance Risk

- 1. Any postmarket information to suggest reprocessed SUD may present an increased risk of injury vs. new SUD?
- 2. Could failure of reprocessed SUD cause death, serious injury or permanent impairment?
- 3. Does SUD contain any materials, coatings or components that may be damaged or altered by reprocessing/resterilization?
- 4. Are there recognized consensus performance standards, CDRH guidances, etc., to help determine if performance has been altered?
- 5. Can visual inspection reveal any performance problems?

RPS -- 3 classes of risk:

- High
- Moderate
- Low

Examples of risks for some SUDs:

List of Frequently Reprocessed SUDs

Medical Specialty/Service	Device	Regulation #	Exempt (Y/N)?	Type of Premarket Submission	Class (I, II, III)	Procode	Risk Category
Cardiovascular	Angiography catheter	870.1200	N	510(k)	II	DQO	high
	blood pressure cuff	870.1120	N	510(k)	II	DXQ	low
	cardiac ablation catheter	Unclassified	N	PMA	III	LPB	high
	cardiac guidewire	870.1330	N	510(k)	II	DQX	high
	compressible limb sleeve	870.5800	N	510(k)	II	JOW	low
	Electrophysiology recording catheter	870.1120	N	510(k)	II	DRF	high
	intra aortic balloon catheter	870.3535	N	510(k)	III	DSP	high
	needle	870.1390	N	510(k)	II	DRC	high
	percutaneous transluminal coronary angioplasty (PTCA) catheter	Unclassified	N	PMA	III	LOX	high
	percutaneous transluminal angioplasty (PTA) catheter	Unclassified	N	510(k)	II	LIT	high
	syringes	870.1670, 870.1650, unclassified	N	510(k)	II	DXT	high
	trocar	870.1390	N	510(k)	II	DRC	moderate

Proposed SUD Enforcement Guidance

- Registration and Listing (21 CFR Part 807)
- MDR requirements (21 CFR Part 803)
- Labeling requirements (21 CFR Part 801)
- Manufacturing requirements under the Quality Systems regulation (21 CFR Part 820)
- Premarket notification and approval requirements (21 CFR Parts 807 and 814)
- Medical Device Tracking (21 CFR Part 821)
- Medical Device Corrections and Removals (21 CFR Part 806)

1. Registration and Listing:

- Owners and operators of establishments who manufacture devices, including reprocessing, must:
  - Register their establishment with FDA (Form FDA-2891) and
  - List each device (Form FD-2892)

2. Medical Device Reporting (MedWatch 3500A)

- Must report device-related Deaths, Serious Injuries, and Malfunctions
  - Report within 30 calendar days after becoming aware of the event.
  - Report within 5 work days after becoming aware when event involved a remedial action (e.g., removal of device from service; repair of device; patient monitoring, etc.).
  - Submit baseline reports.
  - Submit annual updates as necessary.

3. Medical Device Tracking:

- Purpose: to promptly locate devices in commercial distribution in the event corrective actions or notifications about the device are necessary.

- Is triggered by a specific FDA Tracking Order to the manufacturer or reprocessor.

4. Medical Device Corrections and Removals:

- Must submit within 5 days, a written report to FDA of any corrections or removal of a device that pose a risk to public health.

  - Correction - the repair, modification, adjustment, relabeling, destruction or inspection of a device, including patient monitoring …

  - Removal - moving the device to another location for the purpose of repair, modification, adjustment, relabeling, destruction, or inspection...

5. Quality System Regulation:

- Governs the methods used in, and the facilities and controls used for the design, manufacturer, packaging, labeling, storage, installation, and servicing of all finished devices.

- Process Validation!

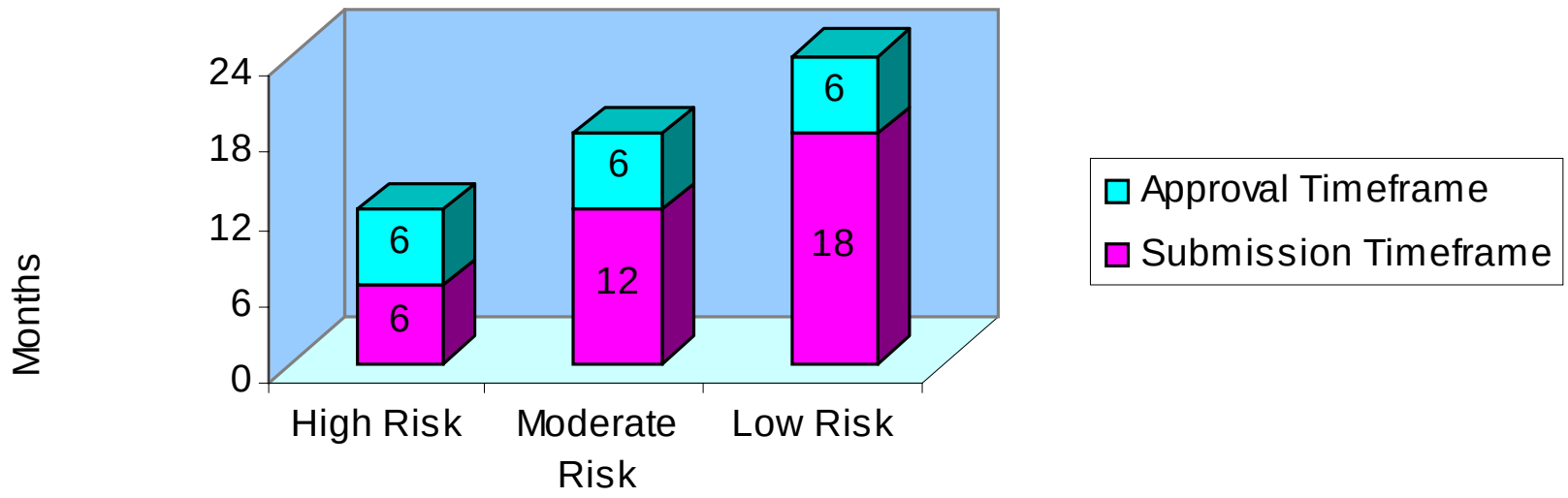
6. Labeling:

- General labeling requirements on the device and on all packaging not just adequate directions for use.

7. Premarket requirements

510(k)
or
PMA

PROPOSED ENFORCEMENT TIMELINE



Enforcement Discretion for Hospitals:

- FDA will wait 6 months after issuance of final guidances before enforcing:
  - Registration & Listing
  - MDR requirements
  - QS regulation
  - Tracking
  - Corrections and removal

Third Party Reprocessors:

- FDA will continue to actively enforce all non-premarket requirements